

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Valerio Cioli
Title : SUBLINGUAL ADMINISTRATION OF
NON-STEROIDAL ANTI-INFLAMMATORY
PHARMACOLOGICAL SUBSTANCES
Application No. : 10/560,337
Filing Date : December 9, 2005
Docket : BUG5-39170
Customer No. : 00116

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is in response to the Restriction Requirement mailed on January 9, 2008. Applicant responds to the restriction requirement as follows:

First - The Applicant strongly **traverses** the Examiner's conclusion that no unity of invention exists, on the following basis:

a) The application is directed to **sublingual pharmaceutical formulations** of non-steroidal anti-inflammatory active substances (FANS), i.e. a well-known **omogeneous** class of compounds which has **the same or similar** pharmacological action and way of interacting with the organism. Thus there is indeed a general inventive concept in the designation of one such homogeneous class of compounds;

b) The sublingual administration route acts, thanks to the fast disintegration of the formulation in the oral cavity, to considerably reduce (around 50%, see disclosure) the administered dose for all the FANS, and in such a way enhances effectiveness and security of use.

Thus there is indeed a general inventive concept in the designation of one such homogeneous class of compounds for sublingual use. For these reasons, Applicant strongly traverses the restriction requirement and requests that it be withdrawn.

Second - Nevertheless, the Applicant elects the following:

First Species Election

Species elected : Applicant elects the compound "nimesulide". Claims 11-21 are readable on this species.

Second Species Election

Species elected : absence of an excipient. Claims 11-13 and 17-21 are readable on this species.

Third Species Election

Species elected : absence of a lubricant. Claims 11-16 and 19-21 are readable on this species.

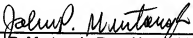
Fourth Species Election

Species elected : absence of a sweetener. Claims 11-18 and 21 are readable on this species.

If any additional fees are required by this communication, please charge such fees to our Deposit Account No. 16-0820, Order No. BUG5-39170.

Respectfully submitted,

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